

Charles E. Wright, MD
Medical Director

LifeLink of Florida

20
Liz Lehr, BSN, MHA
Vice President/Executive Director

Charles E. "Sonny" Sanders, Jr., MD
Associate Medical Director



"With Your Help, Life Goes On..."

March 24, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:

"Quality Assessment and Performance
Improvement (*adverse events*) §486.348

As Executive Director of an OPO as well as a nursing professional with 22 years of experience, I recognize the importance of a strong Quality Assessment and Performance Improvement (QAPI) program. Ongoing analysis is vitally important to an organizations ability to learn and improve from adverse events. As such, I applaud CMS' commitment in the proposed regulations that should be used to guide an organization to constant improvement. Our organization has procedures in place whereby adverse events are monitored, analyzed and corrective measures put in place. Any organization should have room for improvement and our organization is no exception. However, I am concerned about adverse event reporting as described below in the proposed regulation.

42CFR §486.348 states "As part of the QAPI process, an OPO would be required to investigate adverse events and complete a thorough analysis. An adverse event for an OPO could be caused by mismanagement of a donor, failure to test organs for infectious disease, failure to compare the blood type of the donor with the blood type of the intended recipient, or mixing up the labels on packaged organs."

"In addition, we are proposing that an OPO be required to report an adverse event to us..."

My concern in the CMS proposed reporting of adverse events is the lack of a clear definition of which adverse events are to be reported. One could argue that adverse events can be graded in their significance and, in the absence of standardized definitions (as defined by the OPO or transplant industry) it is nebulous as to what constitutes an error to be reported to CMS. More importantly, however, is the question of to whom will these reports be open? Will this be a public document? This is not clearly outlined and in the absence of knowing exactly who would be privy to confidential donor and/or recipient information, the OPO would be uncomfortable with providing such information. As an OPO Director and advocate for the families donating, these questions must be addressed prior to commencement of reporting in order to assess and limit liability concerns for our organization.

Respectfully,

Liz Lehr, BSN, MHA
Senior Vice President / Executive Director
LifeLink of Florida



A Donate Life Organization

409 Bayshore Boulevard, Tampa, Florida 33606 ♦ 813-348-6308 ♦ 1-800-350-9130 ♦ Facsimile 813-349-6512 ♦ www.lifeflinkfound.org

adverse events are to be reported. One could argue that adverse events can be graded in their significance and, in the absence of standardized definitions (as defined by the OPO or transplant industry) it is nebulous as to what constitutes an error to be reported to CMS. More importantly, however, is the question of to whom will these reports be open? Will this be a public document? This

LifeLink Foundation



A not-for-profit corporation dedicated to serve patients in need of transplantation therapy.

March 24, 2005

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 Attention: CMS-3064-P
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 Baltimore, MD 21244-8015

HARDCOPIES SENT VIA US MAIL

RE: "Appeals" 42 CFR §486.325

These comments have been written to address certain changes recommended in the Medicare and Medicaid Programs Proposed Rule covering Conditions for Coverage for Organ Procurement Organizations (OPOs). In the Proposed Rule referenced above, CMS advocates the removal of a paragraph titled "Appeal right" from the current version of 42 CFR section 486.325(c), which reads as follows:

"The OPO may appeal the termination in accordance with the provisions set forth in Part 498, which sets forth appeals procedures for determinations that affect participation in Medicare and Medicaid programs"

The Proposed Rule justifies the elimination of the existing appeal rights afforded other Medicare providers and suppliers by arguing that the current appeal process is too long, uncertain, and disruptive to the OPO community's ability to raise the level of organ donation and; therefore, must be expedited. The Proposed Rule further justifies the elimination of the existing appeal rights afforded other Medicare providers and suppliers by arguing that OPOs are too unique to be considered a Medicare supplier. In fact, the Proposed Rules recommends removing OPOs from the definition of suppliers found at 42 CFR Section 498.2.

In attempting to make this change, the Centers for Medicare and Medicaid Services (CMS) is sacrificing due process in favor of speed and is creating a discriminatory appeals process that severely disadvantages the OPO provider community. The current appeal rights available to OPOs under the Part 498 regulations have not prevented the de-certification of OPOs due to involuntary termination of participation agreements; rather, they have served to guarantee OPOs the same rights provided other suppliers and providers participating in Medicare and Medicaid programs. Additionally, the Part 498 appeal rights currently available to OPOs undergoing de-certification have not prevented the number of organs made available annually for transplantation on a national level from increasing every year since 1988.

Under the Part 498 regulations, a prospective supplier, which is dissatisfied with an initial determination by CMS, may request reconsideration of that determination. These regulations further state that any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an Administrative Law Judge (ALJ) and that any supplier or perspective supplier dissatisfied with the hearing decision of the ALJ may request Departmental Appeals Board review of the ALJ's decision.

This current appeal right of OPOs under Part 498 can include up to three appeal steps summarized as follows:

1. **Request for Reconsideration:** a written request within 60 days of determination for reconsideration based on relevant facts and evidence (Sec. 498.22 & 498.24);
2. **Request for Hearing Before ALJ:** a written request within 60 days of reconsideration ruling requesting a hearing before an ALJ (Sec. 498.40); and
3. **Request for Departmental Appeals Board Review:** a written request within 60 of notice of the ALJ's decision for review by the Departmental Appeals Board (Sec. 498.82).

As I understand the Proposed Rule, the three steps of reconsideration, hearing, and review that are currently available to OPOs as Medicare suppliers would be replaced with a single step. Under the Proposed Rule, an OPO facing de-certification due to involuntary termination or non-renewal can only appeal this determination by submitting an appeal to a CMS hearing officer who makes a the final determination as to whether the de-certification determination should be up-held or reversed.

The Proposed Rule glosses over this significant change to OPO appeal rights by stating that they are "fair" and "expeditious." Given the significant loss of due process and appeal rights experienced by an OPO under the Proposed Rule, it is hard to argue that the single step appeal process outlined is not expeditious. However, it is relatively easy to argue that appeal rights recommended in the Proposed Rule are unfair and unreasonable.

Due process is generally understood to include the concept of "a meaningful opportunity to be heard." The new appeal rights proposed by CMS significantly diminish the due process available to OPOs by eliminating two meaningful opportunities to be heard by parties independent of the agency (namely an ALJ and the Departmental Appeals Board) and by replacing these two opportunities with one less meaningful opportunity to be heard by a CMS hearing officer who could easily be subject to undue agency influence.

Administrative Law Judges are independent, impartial adjudicators in the administrative process and their involvement in an appeal ensures a separation of the adjudicative and prosecutorial functions. By inserting a CMS hearing officer into the appeal process, CMS is asking a subordinate employee to act as both prosecutor and judge, eliminating the segregation of duties guaranteed under the current appeal rights. Moreover, the inherent flaws in the proposed appeal process could allow de-certification appeals to devolve into sham proceedings where the CMS hearing officer is simply an instrument and mouthpiece of CMS unwilling to objectively evaluate evidence. While this would certainly produce an expeditious result; it hardly seems fair.

Under the Proposed Rule, OPOs would not only lose the independent review provided by a hearing before an Administrative Law Judge, they would also be denied access to a Departmental Appeals Board Review, which is a level of appeal routinely afforded other Medicare program participants. The Departmental Appeals Board (DAB) is an independent office established to provide conflict resolution services. The Medicare Operations Division of the DAB supports Administrative Appeals Judges who act as the Medicare Appeals Council for review of decisions by ALJs in Medicare entitlement and coverage cases.

Within the Proposed Rule, an attempt is made to make a distinction between OPOs and other entities supplying goods or services to the Medicare program. This distinction is ineffective and fabricated to support a reduction in appeal rights. A kidney transplant event routinely involves several organizations that participate in the Medicare program as suppliers or providers: an OPO coordinates organ recovery and placement; the organ is recovered in a donor hospital; an independent laboratory performs tissue typing and matching, and the transplant occurs in a transplant center. Each of these organizations plays a vital role in supplying transplant services to Medicare beneficiaries. They all incur significant costs to ensure that they can effectively provide this service; and yet, under the Proposed Rule, OPOs would be the only transplant service supplier singled out as being unworthy of the appeal right afforded the other participants in this chain of service.

In order to avoid this discriminatory result, OPOs should continue to be afforded the appeal rights provided under Part 498. Furthermore, an OPO appealing a de-certification determination should receive a contract extension until the appeal process is completed. Concerns over "uncertainty" and lost "effectiveness" have not prevented CMS from guaranteeing other organizations involved in providing lifesaving services to Medicare beneficiaries the due process granted under Part 498.

In addition, the shortened period for decertification, termination, and appeal recommended in the Proposed Rule ignores or undervalues the significant cost incurred and effort expended in providing organ procurement services and implies that these services can be easily turned on or off. OPOs like most healthcare entities must infuse significant amounts of capital into forming as legal entities, into acquiring qualified staff, into purchasing supplies and equipment, into paying donor hospital bills, into covering rents, and so on. This level of investment, which mirrors the investment made by other Medicare program participants, demands an equitable appeal process before termination occurs.

Thank you for reviewing my comments. Should you have questions about my comments or should you require additional information, please feel free to contact me by calling me (813-383-6009) or by e-mailing me (bryan@lifelinkfound.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Bryan McDonald", with a stylized flourish extending from the end.

Bryan McDonald, CPA, Macc
Chief Financial Officer
LifeLink Foundation

Charles E. Wright, MD
Medical Director

LifeLink of Florida

Liz Lehr, BSN, MHA
Vice President/Executive Director

Charles E. "Sonny" Sanders, Jr., MD
Associate Medical Director



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HARDCOPIES SENT VIA U.S. MAIL

**Response Comments Regarding CMS Proposed Regulations On:
"OPO Role in Living Donation"**

"OPO Role in Living Donation"

As Executive Director of an independent OPO in Florida I would like to comment on the role of the OPO in living donation. OPO's are the experts in deceased donation.

"...we believe that living donation should remain a medical decision between individuals interested in donating and their physicians. However, in view of the increasing importance of living donation, we are specifically requesting public comments on what role, if any, OPOs should play in living donation."

Living donation programs have been growing across the US. Developments in transplantation techniques have made the option of kidney living donation even more attractive to waiting patients and their potential donors. Living donation programs at Transplant Centers contribute to other donation efforts by increasing awareness and community support of organ donation. Along with transplant recipients, living donors can be persuasive advocates for organ donation.

We too believe that the medical decisions between individuals interested in donating and their physicians should remain just that. Transplant centers should have policies and protocols in place to fairly and objectively evaluate all persons interested in donating, whether known or anonymously. The Transplant centers should have adequate staff to evaluate all issues arising in such instances. The OPOs should remain advocates for donation in their current role, from brain dead and DCD situations, and should not be placed in the additional role of allocating anonymously donated organs from a certain transplant center.

Respectfully,

Liz Lehr, BSN, MHA
Senior Vice President / Executive Director
LifeLink of Florida



A Donate Life Organization

Charles E. Wright, MD
Medical Director

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Liz Lehr, BSN, MHA
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March 24, 2005

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Baltimore, MD 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Proposed Regulations On:
"Relationships with Tissue Banks and Requesting Consent" §486.322

As Executive Director of LifeLink of Florida, an independent OPO who shares formal working agreements with LifeLink Tissue Bank and Central Florida Lions Eye and Tissue Bank, I am very concerned about the proposed CMS regulations as they relate to relationships with tissue banks.

42CFR §486.322 states:

"We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors:...(2)Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."

One of the hallmarks of successful organ, tissue and eye recovery in our service area has been formalized working relationships that stress joint accountability and have been forged over many years. The tissue banking industry, unlike organ donation is a rapidly growing and changing industry. In our state, new tissue banks are emerging at a rapid rate. Some of these organizations have very little to no previous experience with tissue banking or recovery practices. There are numerous "organizations" in our state that are for-profit, recovering tissue from donors outside industry (AATB) standards and utilizing these tissues in lucrative and profitable ways.

Our foundation supports a not-for-profit Tissue Bank, one that maintains AATB standards in tissue screening, retrieval, processing and donor reconstruction. Working with this tissue bank has a number of advantages. The Coordinators obtaining consent from families are able to tell donor families the uses of all tissues that are donated and that they may restrict certain tissues. Due to our shared formal working relationships and joint accountability our coordinators are comfortable making assurances to donor families on what tissues will be recovered and how the body will be reconstructed. If the OPO is forced to obtain consent for tissue banks with which we have no agreement, we no longer have the ability to ensure what we tell the family will occur, does. It places legal liability upon the OPO and with no knowledge of a tissue banks internal standards or practices we cannot speak knowledgeably about how donated tissues will be utilized.

Respectfully,

Liz Lehr, BSN, MHA
Senior Vice President / Executive Director
LifeLink of Florida



A Donate Life Organization



Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 Attn: CMS-3064-P
 PO Box 8015
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**Response Comments Regarding CMS Proposed Regulations On:
 Re-certification and Competition §486.316**

On behalf of St. Joseph's Hospital, Tampa Florida, I would like to register our strong opposition to the CMS rule that proposes opening all OPO service areas for competition at the end of every re-certification cycle, whether they meet the standard or not. I believe this regulation is theoretical and untested, with the potential for suppressing the sharing of best practices between OPOs. This sharing environment fostered by the national HHS Collaborative Organ Donation Breakthrough Collaborative has proven to be instrumental in increases in organ donation across the nation.

As our hospital's Team Leader for the Collaborative initiative I am proud of our progress over the past year of Collaboration involvement. St. Joseph's Hospital is a level two trauma center servicing a diverse population through one of the busiest emergency and trauma centers in the state; annually serving over 90,000 adult and pediatric visits. Over the past five years, we have significantly contributed to donation with 94 donors. While we recognize the significance of the donors and the many lives saved or enhanced, our conversion rate for the same five years falls short at 53%. It is our goal to utilize best practices, improve our process and maximize our donation potential, increasing our conversion rate to at least 75%. To date, our institution has realized an increase of 38% in 8 months as compared to the same time frame last year. In the future this may not be possible if OPOs do not feel free to communicate openly with the potential to negatively impact approximately 87,000 individuals nationally awaiting organ transplantations; 3000 of which are Floridians.

The Collaborative's fundamental premise is to challenge both the hospital and organ procurement organization communities, to increase the number of organs available for transplant, and to spread known best practice models. Our team has been encouraged by the progress we have realized through participation in and adoption of practices learned through the Collaborative. The integrated partnership between the OPO and the hospital communities nationwide is bringing about an increased conversion rate and understanding of best practices.

St. Joseph's Collaborative team has adopted many shared best practices learned through the Collaborative to assist with improving our donation process, including:

- Implementation of the clinical trigger cards - criteria to assist in more timely and consistent referrals to the OPO
- Including high-level hospital and physician "champions" to ensure organ donation as a priority for our hospital
- Scripting to assist our staff better communicate with families of potential donors

In our partnership with our OPO, LifeLink of Florida, we continue to share and learn new methods to increase and sustain our conversion rate.

As a hospital that has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule. On behalf of our Collaborative team, and St. Joseph's Hospital, I want to request that this CMS proposal be revised to support the proven fundamental principles of the Organ Donation Breakthrough Collaborative and its many demonstrated best practice successes.

Sincerely,



Margie Butler A.R.N.P.
Director of Patient Care Services
St. Joseph's Hospital
Tampa, Florida 33607

Don Snell
*President &
Chief Executive Officer*



April 4, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: Recertification and Competition §486.316

I am writing in reference to the proposed regulation for Conditions for Coverage for Organ Procurement Organizations. On behalf of MCG Health, Inc., I would like to take the opportunity to express my concerns with the regulatory proposal. The proposed regulation will transfer the focus from transplant recipients and donor families to a competitive culture among existing Organ Procurement Organizations (OPO). The current regulation allows for recertification if an OPO is performing to standards. The new regulation calls for recertification every four years and open competition that allows a new OPO to bid on an existing service area even if the OPO has been successfully supporting organ donation. This affects relationships built over time with hospitals and ultimately could adversely affect patients.

MCG Health System has accepted the challenge issued by the Department of Health and Human Services (HHS) Organ Donation Breakthrough Collaborative to increase organ donors, thereby potentially helping the 87,000-plus patients waiting on transplants in the United States. The HHS initiative promotes the sharing of best practice models to increase organ donation rates throughout the country. However, the proposed regulation will have an adverse effect on the Organ Donation Breakthrough Collaborative by promoting competition rather than sharing of best practice models. The collaborative inspires innovative activity among the participating hospitals to increase organ donation rates by integrating the best practice models into the hospitals' day-to-day activities. The collaborative also encourages a positive partnership between the hospital and the OPO to increase awareness of organ donation in the hospital and surrounding communities.

MCG Health System is composed of MCG Health, Inc., the not-for-profit corporation that manages the clinical facilities and services, the Medical College of Georgia and the Physicians Practice Group. MCG Health, Inc. includes a 483-bed adult hospital, a 149-bed Children's Medical Center and an Ambulatory Care Center with more than 80 outpatient clinics in one setting. We house a 13-county Level 1 trauma center, a Neuroscience Center of Excellence as well as a kidney and pancreas transplant center.

MCG Health, Inc.

1120 15th Street, BA-3306, Augusta, Georgia 30912 706-721-6569 Fax 706-721-6572 MCGHealth.org

Medical College of Georgia Health System

As a part of the transplant community, the health system recognizes the importance of increasing donation rates. Prior to the HHS initiative, our hospital donation rates had dropped from years past. However, in the last 12 to 18 months since participating in the HHS initiative, the health system has quadrupled organ donation from four organ donors in 2003 to 16 organ donors in 2004. The best practice models shared through the initiative have resulted in an increase of organ referrals, increase of timely organ donor referrals, an increase in appropriate requesting and a decrease in missed eligible referrals. Although the initiative has been successful, we have not met the 75 percent conversion rate goal. Our conversion rate is 40 percent. MCG Health System and LifeLink of Georgia will collaboratively use the fundamentals set forth in the HHS initiative to meet the conversion rate goal.

The HHS initiative has allowed the already strong relationship with LifeLink of Georgia to develop into a much stronger and mutually trusting relationship. Implementing the untested competitive regulations set forth by the Center for Medicare and Medicaid Services could disrupt the existing OPO service areas and destroy the trust already established. This has the potential to decrease organ donation rates instead of increasing the number of organs for transplantation. Therefore, I urge CMS to implement similar HHS initiative models in place of the proposed competitive model. The Organ Donation Breakthrough Collaborative creates a culture of sharing success rather than competing for success by allowing successful best practice models to nurture OPOs that have fallen short in their service area.

Organ donation is a significant priority for our organization, and we will continue to strive for best practices in a model of collaboration. Thank you for allowing MCG Health System the opportunity to comment on this proposed regulation.

Sincerely,

A handwritten signature in dark ink, appearing to read "Don Snell" followed by a stylized flourish or initials.

Don Snell
President/CEO
MCG Health, Inc.



March 28, 2005

Centers for Medicare and Medicaid Services
 Department of Health and Human Services
 Attention: CMS-3064-P
 P. O. Box 8015
 Baltimore, MD 21244-8015

"Recertification and Competition" §486.316

As CEO of The Medical Center, COO of Columbus Regional Healthcare System, and a LifeLink of Georgia Advisory Board member, I would like to address the proposed Centers for Medicare and Medicaid Service (CMS) rule 3064-P: Conditions for Coverage for Organ Procurement Organizations. These proposed regulatory changes will negatively impact an initiative known as the Organ Donation Breakthrough Collaborative. The Collaborative is a highly successful initiative started by the Department of Health and Human services (HHS). Its intent is to dramatically increase donation and promote unity among the Organ Procurement Organization (OPO) and the hospital communities.

Last fall, The Medical Center was selected as a Collaborative participant and has partnered with Georgia's Organ Procurement Organization (OPO), LiveLink of Georgia, to improve our hospital's donation and conversion rates. We have been working collaboratively with LifeLink and together continue to implement the best practices shared through the Collaborative's initiatives.

The new regulation CMS is proposing, is untested, and will promote a negative environment where OPOs will be competing for the opportunity to serve its service area. This competitive model could negate the hard work of the Collaborative initiative by forcing OPOs to no longer share the best practices for fear of what the future may hold.

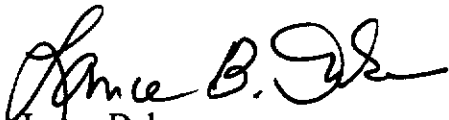
During the 2004 fiscal year, working collaboratively with LLGA, we recovered 69 organs for transplant. These 69 transplantable organs are the result of 17 donors, the highest number for any 12-month period at The Medical Center throughout the last 5 years. Without The Medical Center collaborative team working so closely together to implement the proven practices, this number may not have been achievable. As you can



see, the collaborative effort is exemplified in the number of organs we were able to recover.

The national initiative has a proven record of outstanding results, as well as committed and competent leaders throughout the large hospitals and OPOs across the nation. As a hospital that has been involved with the important work of increasing the number of organs available for transplant and transplant center that has enjoyed an increase in the availability of transplantable organs, we strongly support the Collaborative model in place of the untested, competitive model that CMS proposes in the rule.

Sincerely,



Lance Duke

Chief Executive Officer
The Medical Center
Chief Operating Officer
Columbus Regional Healthcare System

LD/dm



80 Jesse Hill Jr. Drive S.E., Atlanta, Georgia 30303-3050

April 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: "Recertification and Competition" §486.316

I am writing to express my concern with the proposed Centers for Medicare and Medicaid Service (CMS) rule 3064-P: Conditions for Coverage for Organ Procurement Organizations. This proposed regulatory action would hinder the efforts of the Organ Donation Breakthrough Collaborative initiated by Secretary Tommy Thompson. As participants in the Collaborative, we feel that we have gained incredible knowledge by sharing Best Practices from other hospitals and organ procurement organizations throughout the country. It is my opinion this proposed regulation would interfere with the great strides this initiative has made in the field of donation and transplantation.

Grady Health System is one of the largest public hospitals in the Southeast -- and includes Grady Memorial Hospital, Hughes Spalding Children's Hospital, 10 neighborhood/airport health centers and the only level one trauma center within a 100-mile radius. In September 2003, Grady was selected to participate in the first Organ Donation Breakthrough Collaborative. We considered it a great honor to partner with our local organ procurement organization, LifeLink, and to work closely with other large hospitals throughout the country to improve the conversion rate at our facility.

Also, several years ago we partnered with LifeLink to place a full-time In-House Coordinator in our hospital. This individual, a LifeLink employee, has been a wonderful addition to our "team". They are a valuable resource to our hospital and have contributed to the growth of our donation program. In the last five years, we have had a total of 62 organ donors that resulted in 191 transplants. Although our conversion rate has remained steady at approximately 52%, we are dedicated to continuing to identify and implement best practices to improve our conversion rate to at least 75%.

The action that CMS is proposing is untested, theoretical and competitive and would have negative outcomes in the long-term. As we have seen through the Collaborative, the sharing of ideas has improved donation rates throughout the country. As a result of the Collaborative, the number of deceased donors has increased by almost 11%. The practices used by organ procurement organizations and large hospitals to generate these high rates can be replicated. The Collaborative has helped OPOs and large hospitals to close that gap rapidly and as a result has saved or enhanced thousands of lives each year.

Grady Memorial Hospital is committed to pursuing every opportunity to increase the number of organs available for transplant. We strongly support the Collaborative model in place of the untested, competitive model that CMS proposes in the rule.

Sincerely,

Dr. Rhonda A. Scott, PhD, RN, CS
Chief Nursing Officer/Senior VP Patient Care Services

28

OFFICE OF THE MEDICAL EXAMINER

COBB COUNTY, GEORGIA

Brian S. Frist, M.D.

Chief Medical Examiner

Joseph L. Burton, M.D.

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Forensic Pathologist

M. A. Cospers

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March 30, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

HARDCOPIES SENT VIA U.S. MAIL

Response Comments Regarding CMS Regulations On:

"Relationships with Tissue Banks" §486.322

As Medical Examiner for Cobb County of Georgia and an advocate for donation, I would like to voice my concern regarding the proposed CMS regulation. This regulation may interfere with medical examiner investigations and hamper organ procurement operations in conjunction with the medical examiner.

42CFR §486.322 states *"We propose requiring OPOS to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."*

The Office of the Cobb County Medical Examiner (Cobb ME) has taken an active role in enabling families in Cobb County to fulfill the wishes of donors for many years. We have made donation possible through a partnership with LifeLink of Georgia and without question, have allowed them to secure informed consent and coordinate the donation process. In calendar year 2004, there were 90 organ and/or tissue donors that fell under the jurisdiction of the Cobb ME, an accomplishment of which we are very proud.

I do not recall a time when we were not able clear a potential donor for organ donation, in difficult cases, my staff has accompanied LifeLink to the operating room to ensure the integrity of our investigation and still allow LifeLink of Georgia to facilitate the gift of life. The 90 cases referenced above, as well as the many from past years, occurred because of a partnership built over time with extensive communication, established procedures, and certainly trust and respect between LifeLink of Georgia and the Cobb ME. When a request is made for any tissue or organ, we are familiar with their process, have confidence that the family has been counseled, consent secured from the appropriate individual(s), and of utmost importance, confidence that our forensic investigation will not be compromised by donation.

My understanding of the proposed regulations is the OPO will be required to work with any "willing" tissue bank and as I further interpret, be required to obtain informed consent on behalf of the "willing" tissue bank. If the intention of this regulation is to require an OPO to request and obtain an informed consent of behalf of a tissue bank that does not share the same policies/practice, this could place the OPO in a difficult legal and ethical position with the donor family. This may also place the medical examiner's office in a difficult position where we must choose what tissues can be released based on our knowledge of the recovering tissue agencies practices.

While, I support the requirement that the OPO pass on referrals to the hospital's chosen tissue recovery provider. The OPO should not be required to obtain consent for a tissue bank with which it does not have a working relationship.

Respectfully,

A handwritten signature in black ink, appearing to read 'B. Frist', with a stylized flourish at the end.

Brian S. Frist, M.D., M.E.



GEORGIA EYE BANK INC.

March 29, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

As President and CEO of Georgia Eye Bank and a member of the LifeLink of Georgia Advisory Board, I am writing to you to voice my concern regarding the proposed CMS regulation, 42CFR §486.322 which states "*We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) obtaining informed consent from families of potential tissue donors in the absence of a donor document; and...*" This proposed regulation may interfere with current practices regarding eye, tissue and organ donation if OPOs are required to request on behalf of all tissue banks.

We have a long-standing working relationship with LifeLink of Georgia utilizing a joint consent form with shared requestors for eye and tissue and have done so prior to the Conditions of Participation of 1998. Based on this long-standing relationship, shared values, and joint educational endeavors, we know that when a request is made for eye, tissue, and/or organ donation, the family has been counseled, consent is secured from the appropriate individual(s) and they are informed of the intended use of those gifts. My concern with this proposed regulation is the idea that you will be requiring the OPO to request on behalf of tissue banks other than their own or those they have working relationships with.

No organization should be forced to work with another organization, the practices of the tissue bank may be inconsistent with that of the OPO and may not meet their standards. In the area of consent, it is critical that the partnering organizations have the same standards, and this is not always the case. If the intention of this regulation is to require an OPO to request and obtain an informed consent of behalf of a tissue bank that does not share the same policies/practice, this could place the OPO in a difficult legal and ethical position with the donor family.

While I acknowledge the requirement that the OPO function in the role as "gate-keeper" and pass referrals on to the entity the hospital has selected as their tissue provider, any requirement beyond this should only occur when there is a formal, mutual agreement.

Respectfully,

A handwritten signature in black ink, appearing to read "B. H. Varnum", with a long horizontal flourish extending to the right.

Bruce H. Varnum
Chair, Board of Trustees
President/CEO



Florida Department of
Law Enforcement

Guy M. Tunnell
Commissioner

Medical Examiners Commission

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<http://www.fdle.state.fl.us>

March 29, 2005

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTENTION: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

In Re: Response Comments Regarding CMS Regulations On:
"Relationships with Tissue Banks" 42CFR §486.322

Dear Sirs:

In 2003, Florida's Medical Examiners Commission – which I chair – adopted Practice Guidelines for Florida's medical examiners which reaffirmed many years of long-standing practices and earlier recommendations from our Commission's *Ethical Advisory Committee*. The guidelines state, "A medical examiner should cooperate with at least one tissue bank, but is not obligated to work with more than one tissue bank." Additionally, the guidelines recommend practices that require long-standing relationships and strong communication with the organ procurement organizations (OPO) and chosen tissue bank. As public servants, medical examiner's offices in general, have neither the staff nor the resources to be required to monitor recovery services or potential consent issues that may arise from working with multiple or unfamiliar tissue recovery agencies which could be mandated by this proposed regulation change.

If the intention of this regulation is to require an OPO to request and obtain an informed consent on behalf of a tissue bank that does not share the same policies and/or practices, this proposal will likely place the OPO in a difficult legal and ethical position with the donor family, and potentially compromise evidence needed to move forward with important forensic investigations. OPOs and medical examiner offices should not be restricted to work with a tissue bank whose practices are not consistent with that of the OPO, particularly as it relates to consent.

Florida's Medical Examiners Commission strongly supports the requirement that the OPO function in the role of "gate keeper," passing referrals on to the tissue bank that the hospital has selected as their tissue provider. Any requirement beyond that should only occur when there is a formal, willing, and mutual agreement which is beneficial to the donor families, hospitals and medical examiners offices in maximizing all donations available for transplant.

Since last year there have been no organ donation requests that were denied by any Florida medical examiner. We do not want to deter, in any way, a system that is working so well.

Sincerely yours,

Stephen J. Nelson, M.A., M.D., F.C.A.P.
Chairman, Medical Examiners Commission

SJN:jkb

OFFICE OF THE
DISTRICT MEDICAL EXAMINER

10TH JUDICIAL CIRCUIT OF FLORIDA
In & For Polk, Hardee and Highlands Counties



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STEPHEN J. NELSON, M.A., M.D.
DISTRICT MEDICAL EXAMINER

March 29, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

In Re: Response Comments Regarding CMS Regulations On:
"Relationships with Tissue Banks" §486.322

Dear Sirs:

As a member of the HRSA Organ Donation Breakthrough Collaborative Leadership Coordinating Council, and of LifeLink of Florida's Advisory Board, I am writing to comment on the following proposed CMS regulation, which will negatively impact organ/tissue recovery and medical examiner operations here in Florida.

42CFR §486.322 states: *"We propose requiring OPOs to have arrangements with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements to cooperate in the following activities, as may be appropriate, to assure that all usable tissues are obtained from potential donors...(2) Obtaining informed consent from families of potential tissue donors in the absence of a donor document; and..."*

If the intention of this regulation is to require an organ procurement organization (OPO) to request and obtain an informed consent on behalf of a tissue bank that does not share the same policies/practice, this will likely place the OPO in a difficult legal and ethical position with the donor family, and potentially compromise evidence needed to move forward with important forensic investigations. OPOs and medical examiner (ME) offices should not be restricted to work with a tissue bank whose practices are not consistent with that of the OPO, particularly as it relates to consent.

For many years, my office has had a long-standing relationship with our OPO, LifeLink of Florida, that is based on strong two-way communication, real-time problem

Centers for Medicare and Medicaid Services
Department of Health and Human Services
In Re: Response Comments Regarding CMS Regulations On:
"Relationships with Tissue Banks" §486.322
March 29, 2005

Page 2

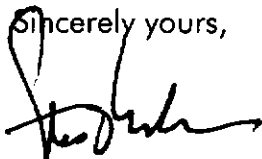
resolution and a commitment that procedures, including securing and obtaining informed consent, are followed consistently. Rarely, are we unable to allow tissue donation to proceed, and we take extraordinary steps to assure every suitable organ is made available for transplant. It is my experience that LifeLink's policies/practices regarding consent, recovery, and reconstruction of the body in accordance with good tissue practices and, more importantly with the wishes of the donor family, are of paramount concern.

In 2003, the Florida Medical Examiner Commission -- which I chair -- adopted *Practice Guidelines for Florida Medical Examiners*, which reaffirmed many years of long-standing practices and earlier recommendations, from the Commission's *Ethical Advisory Committee*. The guidelines state, "A Medical Examiner should cooperate with at least one tissue bank, but is not obligated to work with more than one tissue bank." Additionally, the guidelines recommend practices that require long-standing relationships and strong communication with the OPO and chosen tissue bank. Medical examiner's offices, in general, do not have the staff or resources, as a public servant, to be required to monitor recovery services or potential consent issues that may arise from working with multiple or unfamiliar tissue recovery agencies which could be the unintended result of this proposal.

I support the requirement that the OPO function in the role as "gate-keeper", passing referrals on to the Tissue Bank the hospital has selected as their tissue provider. Any requirement beyond that point, should only occur when there is a formal and "willing" mutual agreement, which will be beneficial to the donor families, hospitals and medical examiner's offices in maximizing all donations available for transplant.

In 2001 there were no organ donation requests that were denied by medical examiners in Florida. I would not want to deter, in any way, a system that is now working so well.

Sincerely yours,



Stephen J. Nelson, M.A., M.D., F.C.A.P.
District Medical Examiner

SJN:jkb



Improving Lives By Delivering Exceptional Health Care

1324 Lakeland Hills Boulevard • P.O. Box 95448 • Lakeland • Florida • 33804 • 863-687-1100

March 28, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

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"Re-certification and Competition" §486.316

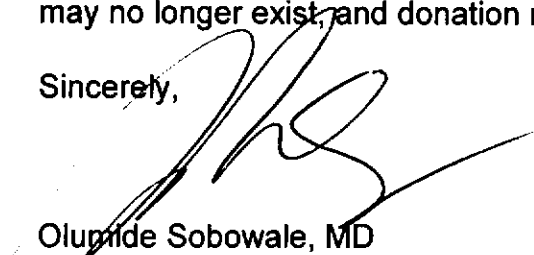
As Chief of Trauma Services at Lakeland Regional Medical Center and Chair of the LifeLink of Florida's Advisory Board's Professional Education Committee, I am writing to express my opposition regarding the proposed Centers for Medicare and Medicaid Service (CMS) rule 3064-P: Conditions for Coverage for Organ Procurement Organizations. This re-certification section proposes to open "...every OPO's service area for competition at the end of every re-certification cycle..." Hopefully, this open communication shut down would not be the intent of the rule. However, it is my opinion that this regulatory rule would severely undermine the progress of the national HHS Organ Donation Breakthrough Collaborative initiative by causing competing OPOs to no longer share best practices. This sharing initiative has proven to be a major success throughout the nation with the result of increases in organ donation across the country.

Lakeland Regional Hospital, a level two trauma center, was identified by HHS as a top performing donor hospital during the planning phase of the national Organ Donation Breakthrough Collaborative. To identify best practices that would be modeled nationwide through the Collaborative, representatives from the Lewin Group, HHS and HRSA organizations interviewed me, along with a number of other individuals at our hospital. Although Lakeland Regional is not formally participating in the Collaborative, we have been proud to contribute and we continue to benefit from integrating other successful practices that have led to continuous improvement of our hospital's conversion rate. To that end, we are committed to collaboratively working with LifeLink of Florida, jointly sharing our efforts that sustain our 75% conversion rate.

I strongly support the open exchange of information as prescribed by the Collaborative model in place of the untested, competitive model that CMS

proposes in the rule. If this regulation should be finalized as currently proposed, the potential for open exchanges of important information and communication may no longer exist, and donation rates would suffer nationally.

Sincerely,



Olunide Sobowale, MD
Chief, Trauma Services
Lakeland Regional Medical Center



Johns Hopkins
Surgical Sciences

600 North Wolfe Street / Balcock 659 / Baltimore, MD 21287-4659
410-955-5743 / FAX 410-614-0466

Department of Surgery
John Hundt, M.H.S.
Administrator

April 4, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Re: "Recertification and Competition" 486.316

To Whom It May Concern:

As Board Member of The Transplant Resource Center of Maryland, I am writing to update you about recent regulatory developments that may severely undermine a critical Department of Health and Human Services (HHS) initiative. Recently proposed regulatory actions by the Centers for Medicare and Medicaid Services (CMS) may harm rather than help the almost 90,000 Americans and over 2400 citizens waiting for organ transplants in Maryland.

The Organ Donation Breakthrough Collaborative has engaged the Organ Procurement Organization (OPO) community and the nations' largest hospitals to increase the number of organs available for transplant. The Transplant Resource Center of Maryland is apart of this exciting initiative that relies on joint accountability and an integrated partnership between OPO's and participating hospitals. The model aims at implementing best practices for increasing the rates of organ donation.

The Organ Donation Breakthrough Collaborative has achieved extraordinary results in the past 12 -18 months. Nationally, the number of deceased organ donors has increased by nearly 11%, and contributed to increases of more than 20% in Maryland. In fact, this collaborative model has been widely studied and cited by the greater healthcare quality improvement community for its effectiveness.

As our hospitals and the Transplant Resource Center of Maryland have worked together as a team over the past year and a half, we have accomplished phenomenal things.

We have some of the busiest trauma centers in the country and have successful transplant programs that rely on the relationships forged by the OPO and the hospital staff.

CMS is proposing an untested, theoretical, competitive model in which every OPO would be completing every four years to continue its service area. This competitive model has the potential of stifling the sharing of best practices between OPO's that have been developed and fostered through the Organ Donation Breakthrough Collaborative.

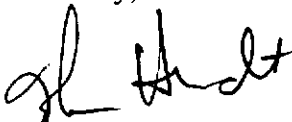
We are proud to say that our team has increased the conversion rates at our OPO to 62%. This success which has saved an addition 100 lives through the provision of addition organs available for transplantation from 2003 to 2004. Some of these gains can be attributed to the exceptional sharing of information across OPO's and hospitals to understand what is working to increase conversion rates in different parts of the country. Sharing best practices is the hallmark of this program. The Transplant Resource Center of Maryland staff has built relationships with hospital, legislative, and regulatory leaders that bridge the gaps that had existed in the past.

The Collaborative Team has used strategies and change concepts to create opportunities in the donation process.

1. Developed clinical trigger criteria – making referrals more timely and consistent.
2. Increase timely death record reviews so that missed opportunities could be addressed.
3. Identified high level hospital “champions” to put organ donation on the priority list for our hospital.
4. Further developed our DCD protocols
5. Continued to model one of the most effective consent processes in the country

As a Board member of the OPO who has been involved with the important work of increasing the number of organs available for transplant, we strongly support the Collaborative model in place of the untested competitive model that CMS proposes in the rule.

Sincerely,



John H. Hundt
Administrator of Surgery
Johns Hopkins Hospital

Richard W. Bauer
Chief Executive Officer

April 22, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3064-P
P.O. Box 8015
Baltimore, MD 21244-8015

Comment – “Requesting Consent”

Dear Sir or Madame:

Please accept this letter as a comment to be considered in response to the rule that has been proposed by CMS to establish conditions for coverage for organ procurement organizations (42 CFR Part 486). In section 486.342, “Condition: Requesting Consent”, it is stated that minimum requirements for consent for donation should include information about organizations that will recover, process and distribute tissue. Within this section (item number 5) the recommendation is to inform the donor family of the “for-profit” or “not-for-profit” status of any such organization that may be involved in the aforementioned activities and to give the donor family the choice of electing which type of organization may receive the tissue, either “for-profit” or “not-for-profit” tissue banks.

Introduction

The difference in Americans’ perceptions of “non-profit” and “for-profit” organizations is quite dramatic and, on the issue of organ/tissue donation, absent any other information, wide majorities of Americans will opt for the “non-profit” almost every time. On the surface, Americans see the term “non-profit” as representing the greater good, and being driven by the same altruism that moves many organ/tissue donors to register in the first place.

In an attempt to bring more clarity to our concern in this area a national survey was commissioned* to determine to what degree “non-profits” would benefit from the proposed CMS rule change, and to what degree other factors should be considered when choosing to donate.

Here are some startling and important pieces of data from the recent survey:

-When given the option of choosing to donate their organs/tissues to a “non-profit” or a “for-profit”, 80% of Americans selected “non-profits”; just 3% “for-profits.”

-Yet, a wide majority (56%) of Americans who initially said they would donate their organs/tissues to a “non-profit” over a “for-profit” also said they would rather base their donation decision on which organization “uses the best technology and creates the most scientific breakthroughs” and not on whether or not an organization was “non-profit” or “for-profit.”

- Furthermore, 49% of Americans who initially favor donating to a “non-profit” over a “for-profit” say they would change their mind if they knew that “executives of the non-profit organization earned six-figure salaries and financial bonuses,” while another 18% aren’t sure how it would affect their decision. Just 33% say they would stick with the non-profit.

- Moreover, Americans don’t believe “for-profit” or “non-profit” organizations should get special treatment “when it comes to collecting, processing, marketing, transporting, or transplanting donated organs/tissue.” Only 15% of Americans feel that “non-profits” should get special treatment. A very large majority (76%) of Americans believe “non-profits” and “for-profits” should “both be treated the same.”

Our comment to the proposed rule will go into greater detail of Osteotech’s concerns, both in terms of how the rule would be received by the public, how the rule fails to account for several key factors in the area of organ/tissue donations, and how the rule can be improved.

Comments

As a steward of the gift of tissue donation, Osteotech believes that the rights of consenting individuals should be respected by providing meaningful information during the consent process that will help them to fulfill their loved ones’ wishes. Additionally, we also believe that society has a right to expect that the gift of donation be utilized in accordance with its altruistic intent, regardless of the tax status of the entities involved.

However, with regard to the minimum requirements for informed consent for tissue donation, Osteotech objects to the inclusion of the phrase “such as for-profit or not-for-profit status” as a mandatory component of informed consent for tissue donation for several reasons.

Osteotech objects on the following grounds;

- **The proposed rule mandates that “for-profit” versus “nonprofit” be a standard component of informed consent for tissue donation, which is a departure from existing guidelines and industry standards.**
 - The Office of Inspector General’s 2001 report, Informed Consent in Tissue Donation, includes the issue under “Additional Elements of Informed Consent” rather than “Basic Elements of Informed Consent”.
 - The American Association of Tissue Banks includes the issue under “Additional Elements of Informed Consent” rather than under minimum requirements.
 - The National Kidney Foundation’s National Donor Family Council issued a position statement in 2001 on tissue donation that includes a discussion of financial considerations, but did not include “for-profit” versus “not-for-profit” language in its Informed Consent Policy for Tissue Donation, also issued in 2000.
 - Organ Procurement Organizations are already operating within the existing guidelines and industry standards.
- **The language in the proposed rule is misleading because it raises donor families’ expectations of the tissue transplantation system to an unrealistic level, and therefore does not constitute a true informed consent.**
 - The terms “for-profit” and “not-for-profit” refer to a tax status.

- “Not-for-profit” companies can and do make a profit.
 - “For-profit” and “not-for-profit” companies are held to the same ethical standards.
 - “For-profit” and “not-for-profit” companies charge similar fees for tissue.
 - Donor families can be led to make a decision in favor of “not-for-profit” companies based on misunderstandings of the above-stated facts.
 - Detailed polling indicates donors and donor families would overwhelmingly select “non-profit” recipients, to the extent that “for-profit” entities could face financial extinction.
 - Americans are confused about the types of entities that should be receiving the tissues such that the reference to “non-profit” vs. “for-profit” does not fully represent the interest they hold in making donation decisions.
- **The potential economic impact of the rule on tissue donation rates and loss of technological resources has not been evaluated.**
 - “For-profit” companies have been largely responsible for the advancement of tissue-transplantation science.
 - A diminished role of “for-profit” companies will impact;
 - Cost (Increased cost related to a decrease in donation rates)
 - Safety (Sophisticated facilities and testing)
 - Effectiveness (the result of investment in research and development)
 - Availability (processing capacity)
 - Ease of use (expanding the clinical options)
- **Federal Supremacy should be invoked to avoid a piece-meal approach on the treatment of “for-profits” and “non-profits” by each state.**

Discussion

For the purpose of this discussion, the term “tissue” refers to musculoskeletal tissue unless otherwise noted, and the terms “tissue bank” or “tissue banking community” refer to musculoskeletal tissue banks.

Language is Misleading

Organ and tissue donation happens because people want to help other people. Donation rates are on the rise because of a joint effort on the part of so many caring professionals within the procurement community who have joined together with the Department of Health and Human Services to educate healthcare professionals about the good that can be done by participating in the donation process. More and more of our friends and neighbors are signing donor cards because of the public education efforts of procurement organizations. Every time someone’s life is enhanced by the gift of donation, it is because a donor and his or her family has put their trust in the donation system. They expect that the gift they have given will be utilized to help someone in need.

The use of the terms “for-profit” and “not-for-profit” is misleading because it raises donor families’ expectations of the transplantation system to an unrealistic level. It makes a distinction that leads donor families to believe that there are companies that are willing and able to fulfill their loved

one's wishes while not generating profit. This creates, at best, confusion on the part of the donor family while they are coping with the loss of a loved one. At worst, it will create an artificial and unfair inhibitor against "for-profit" tissue banks.

As written, the proposed rule will have devastating effects on the tissue transplantation system.

Recent polling of 800 Americans suggests* that donor families do not fully understand that, in reality, "for-profit" versus "not-for-profit" refers to a tax status rather than a company's ability to "make money". The fact is that, while charging similar fees for tissue and operating under the same ethical guidelines, both types of companies can and do generate revenue and profit. In addition, the polling demonstrates that if simply given the choice to select between a "non-profit" or "for-profit" recipient, fully 80% said they would choose "non-profits", while just 3% would elect "for-profits". This is because people have a preconceived notion in their minds about "non-profit" organizations – a notion that would likely result in many "for-profit" entities being driven out of business.

The general public is not well informed about "for-profit"/"not-for-profit" issues in tissue transplantation.

Inevitably, some families will choose to restrict the use of their loved ones' tissue by "for-profit" companies based on the belief that "not-for-profit", or tax-exempt, companies do not generate profit. The recent polling also indicates that donors improperly assume "for-profit" companies generate more revenues (63% thought "for-profits" generate more revenues while just 15% thought "non-profits" generated more revenues). In reality, a "non-profit" like The Musculoskeletal Transplant Foundation (MTF) generated \$228 million in revenue in 2003 while Osteotech generated \$94 million in revenue for the same year. Clearly, the idea among Americans that "for-profits" generate more is inconsistent with reality and further demonstrates the disconnect between attitudes and donor behavior versus how the industry actually functions.

If the proposed CMS language is adopted as drafted, a certain number of consenting individuals will choose to restrict the use of their loved ones' tissues by "for-profit" companies, based on the belief that "not-for-profit" companies, by not generating surplus revenues designated as "profit", are somehow more deserving of the gift of donation. By restricting the amount of tissue sent to "for-profit" companies, patients will be needlessly deprived of the benefit of complex processing technologies that add clinical value to those tissues and that are predominantly available through the services of "for-profit" companies.

The general public feels that the potential for technological advances outweighs any "for-profit" versus "not-for-profit" issues.

According to the same polling, donors electing "non-profit" entities would change their minds if instead, they were asked to donate to the entity that spends more on R&D, scientific studies and technological breakthroughs in the area of organ and tissue donations (58% would want to make their decision based on technology while only 25% would base their decision on an entity's tax status). Companies like Osteotech are leaders in R&D, innovation and technological breakthroughs in the allograft tissue field, yet as drafted the proposed rule would not take this into account for donor consent.

When asked whether “non-profit” or “for-profit” entities should receive special treatment over one another or whether they should be treated the same, an overwhelming 76% of the respondents said they should be treated the same. Only 16% would want to pick one over the other, again demonstrating the confusion that can abound among donor families. Yet as drafted and based on the 80% selection rate for “non-profit” entities by those questioned, the proposed rule would create a de facto regime for preferential treatment of “non-profits”, not the equal treatment for both types of entities that the respondents said they were looking for.

When asked the same question based on tax status (those that pay taxes on revenues/profits versus those that do not pay taxes), an ever greater number (78%) said all groups should be treated the same. Again, this demonstrates most Americans do not understand that “non-profit” is simply a tax filing status.

The general public does not understand the interrelationship between “for-profit” and “not-for-profit” organizations within the tissue banking system.

A completely “not-for-profit” system that is capable of meeting the demands and needs of patients requiring musculoskeletal (MS) tissue transplantation does not exist. The tissue banking system that exists is inherently a combination of the two, and the ability to transplant MS tissue extends far beyond recovery, processing, and distribution, as stated in Section 486.342, item #5.

Here are a few examples from the tissue banking community of how “not-for-profit” and “for-profit” organizations interrelate in the effort to honor the wishes of donors and donor families and provide for the needs of patients who receive tissue.

1. Nonprofit/not-for-profit OPO’s and tissue recovery organizations recover tissue from donors. Tissue recovery is frequently performed in hospital operating rooms. Some of the hospitals where tissue recovery takes place are for-profit. Generally, a fee is paid by the tissue recovery organization to the donor hospital for the use of hospital facilities.
2. Tissue must be transported from the recovery site to the tissue bank that will be responsible for preparing the tissue for transplant. Out of necessity, nonprofit/not-for-profit recovery organizations will utilize for-profit carriers to transport tissue and specimens for testing.
3. Donor testing must be performed according to FDA guidelines in order to ensure the safety of the tissue for transplantation. For-profit laboratories are utilized by “nonprofit” and “for-profit” tissue banks for testing of donor specimens.
4. Tissue, particularly musculoskeletal tissue, must be altered from its original form in order to be beneficial to the patients who receive it. A tremendous, and very costly, amount of technology must be applied to the preparation of tissue for transplant in order to ensure that safe and effective allografts are available for the vast numbers of patients who require them. “Not-for-profit” tissue banks often rely upon the technological capabilities developed by “for-profit” tissue banks in order to enhance or improve the services they provide. For example, many “not-for-profit” tissue banks, in order to meet the demands and needs of surgeons and patients who require tissue for life-enhancing procedures and to contain costs, forward tissue to other “for-profit” tissue banks for specialized processing.

5. Similarly, “not-for-profit” and “for-profit” tissue banks alike rely on the services of for-profit orthopaedic marketing and distributor organizations to offset the costs of employing their own marketing staff to educate surgeons on the use of allograft tissue and distribute tissue to hospitals nationwide.

As has been demonstrated, the role of “for-profit” organizations impacts every phase of the tissue donation process. Thus, given the fact that an unknown number of consenting individuals will limit the use of tissues to “not-for-profit” only, the potential exists for a decrease in tissue donation rates due to the fact that a true “not-for-profit” option within the tissue banking community does not exist to the extent that it could support the needs of the medical community.

The potential economic impact on the tissue donation/transplantation system has not been evaluated.

While the proposed rule, and the associated cost-benefit analysis, appears to focus primarily on the heart, kidney, lung and pancreas, we feel a separate and distinct cost-benefit analysis must be performed by CMS for other transplant tissues. Musculoskeletal, eyes, and a number of other transplantable tissues undergo complex value-added processes – processes designed, engineered, perfected and patented by many “for-profit” companies, without which, the medical profession and scores of patients worldwide would have few other alternatives for medical recovery.

This belief is underscored in the polling. When asked whether there should be a uniform set of rules and guideline for research and transplant of all donated organs and tissue, or whether the rules and guidelines should be different based on the type of organ or tissue being transplanted, a plurality (48%) said each organ/tissue should be treated separately. Just 37% thought they should undergo the same analysis and guidelines for transplanting. This belief that the “one-size-fits-all” approach should not be applied to all organs and tissue means CMS should evaluate the processes, procedures and economic impact of the varying organs and tissues separately. A decision that impacts kidney transplants should not, and cannot, be applied in the same way to musculoskeletal tissue without a separate analysis.

The tissue transplantation process is far more complicated than the organ donation process (See Attachment A). Unlike organs, the ability to transplant donated tissue depends on a significant amount of technology. The FDA Current Good Tissue Practices final rule is evidence of the complexity of the handling and preparation of tissue for transplant. In addition, by the time it is ready to be transplanted, donated musculoskeletal tissue will ultimately take on hundreds of types of final forms because it is not useful to surgeons in the care of their patients in its original form. Each one of those forms requires a different set of technology be applied to the original tissue, and the cost of developing those technologies is quite often measured in millions of dollars.

The result of investment in research, development, and technology impacts both patient outcome and the cost of providing care. For example, lumbar fusion is the most common spinal fusion in the U.S. It is also the most challenging environment within which to achieve good bone healing. Autograft, the patient’s own bone, can be used in the procedure, but is associated with numerous complications (Table 1) associated with the harvesting of the patient’s bone from the ilium, or iliac crest.

TABLE 1

**Estimated Incidence of Clinical Complications Following
Harvest of Bone Graft from the Ilium.**

Major Complications (2.5 – 39%)		Minor Complications (10–40%)	
Neurological injury	0.7 – 39%	Superficial infection	1.2 – 5.6%
Vascular injury	<1.0%	Small seroma/hematoma	1.3-50%
Deep infection	1.0-2.5%	Cosmesis	≤ 3.5%
Large hematoma	0.5-6.0%	Temporary hypesthesia	0.6-38%
Bowel herniation	<1.0%	Mild acute pain	16.5-40%
Fracture	<1.0%		
Pelvic instability with Impaired Gait	1.0-30%		
Chronic pain (≤ 3 mos.)	2.8-37%		

Table 2 and Table 3 demonstrate that, with or without complications, the cost of patient care increases in the absence of the availability of allograft, which is made possible by the technology that enhances the gift of tissue donation and increases its effectiveness.

TABLE 2

Examples of Costs Associated with Complications of Iliac Crest Harvest (\$)	
Severe Pain	\$1,398
Minor Pain	315
Hematoma	5,393
Infection	10,917
Pelvic Fracture	11,093
Cosmesis	499
Wound Dehiscence	6,237

Polly et al¹

TABLE 3

Direct Costs Associated with Autograft Harvest (Spinal Fusion)	
OR Time	\$360*
Anesthesia	351
Surgeon's Time	210
Assistant Surgeon	60
Equipment Costs	60
Closure	310
Length of Stay *	693
	\$2044

*Polly et al¹, Deyo², Watters³

Additionally, when comparing cost, Table 4 demonstrates how the use of allograft reduces the cost of treatment.

TABLE 4

Cost Comparisons of Treatment Modalities ⁺		
Procedure	Modality and Cost of Treatment in Spine Fusion	
	Autograft Iliac Crest Bone	Average Cost of Allograft*
1 Level PLF*		
Cost	\$2,000	\$1,575
2 Level PLF*		
Cost	\$4,000	\$3,150
⁺ Cost of graft materials only		
* PLF = Posterolateral Fusion (Lumbar fusion)		

With regard to economic impact, the most significant impact will be on hospitals, which rely on the tissue banking community to contain costs while providing safe and effective tissue for their patients, and advancing the science of tissue transplantation for the benefit of the communities that they serve. Given the worst-case scenario, tissue supply will be negatively impacted to the extent that the number of tissue banks will be reduced, thus decreasing competition. Because competition is driven by the need to provide technologically advanced and cost-effective solutions for patients, not only would the impact be measured in the increasing cost of tissue to hospitals, but also in the loss of the potential of technologies that hold great promise for medical practice and patient quality-of-life.

Federal Supremacy

Many organs and tissues offered for donation originate in states other than where the final recipient lives or where the hospital performing the final transplant procedure is sited. If a state, county, locality, hospital or organization is allowed to enact legislation or promulgate rules that contain language further restricting which type of organization (“non-profit” or “for-profit”) can receive organs or tissue it could further complicate an already heavily regulated industry and add more hurdles to the overall goal of increasing organ and tissue donations nationwide. Already California has acted with rules that have severely hampered the ability of “for-profit” companies from having access to donated tissue originating in that state. If other states enact similar rules, the effect of the federal rules being advocated by CMS could be undone, creating chaos in the system.

On this point we believe if CMS changes its proposed rule for number 5, as recommended and advocated in our comment, the agency would be justified in clarifying that the new revised rule it implements in regard to the treatment of “non-profit” and “for-profit” organizations should override any state, local or private law or rule that may be stricter or in conflict with this rule and its policy objectives. We provide two reasons for this particular proposal.

First, since CMS is responding to Congressional directives to address the organ procurement process it can be assumed that the broad constitutional authority given to Congress as it relates to interstate commerce (the Commerce Clause, Article 1, Section 8, Clause 3 – Congress has the power “To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes”), means by inference, that the final rule CMS applies as it relates to interstate transport, use, processing and marketing organs and tissue justify federal supremacy, and as it may

relate to any funds being used on Indian reservations or in hospitals receiving funds for health care services to Indians, Alaska Natives and Native Hawaiians.

Second, since the rule is intended to deal with procedures that are ultimately reimbursed using federal funds (Medicare and Medicaid funds) the federal government is entitled and has a duty to ensure no state, county, locality, organization or hospital works to undermine the federal goal of increasing organ and tissue donation, reducing the confusion or disincentives to organ and tissue donation, and insuring hospitals, doctors, OPOs and companies involved in the organ and tissue donation process have a uniform set of rules under which they operate. To allow each entity to further complicate the organ and tissue procurement, processing, marketing and transportation process with its own statutes, rules or regulations is likely to lead to more confusion, forum shopping to circumvent the rules and ultimately the potential for less, not more, organ and tissue donation.

For these reasons we propose the following language be included in the final rule, but only if item number 5 of the current published CMS draft is changed as recommended in our comment (this federal supremacy application would not be necessary if CMS does not amend its draft of the current rule for number 5 because it is already drafted in a way that assumes supremacy because of its harsh affect on the organ and tissue donation process):

“Because the agency is responding to Congressional directives to address the organ and tissue procurement process, and because much of the organ and tissue donation process occurs across state lines, including the identification, procurement, processing, transportation and marketing of organs and tissue, it is assumed Congress used by inference its constitutional power under the Commerce Clause (Article 1, Section 3, Clause 8) to address these interstate issues. In addition, because federal funds are being used to reimburse hospitals or doctors for the organs and tissues used for Medicare and Medicaid recipients, it is within our purview to insist on a uniform federal application of the rules contained herein. Therefore the following language will be added to the final rule:

“No state, county, locality, hospital, person or organization that receives federal Medicaid or Medicare funds or that acquires, transports or offers organs or tissue for use in a state other than where the organ or tissue originated may, through legislation or rule, adopt language adding additional consent or informational requirements to the rules contained herein that: 1) distinguish between “for-profit” and “non-profit” organizations involved in the identification, location, collection, processing, marketing and transportation of organs or tissue; 2) that, in the agency’s opinion, are likely to result in confusion on the part of donors, or their representatives; or 3) that, in the agency’s opinion, are likely to reduce the overall amount of organs and tissue being donated on a national basis. All statutes and regulations created by an entity described in this subsection that affect any organization described in this subsection must submit all such language to CMS for examination and approval consistent with federal statutes and this rule, or spirit or intent of this rule, before any such language may become effective.”

Summary

- The proposed CMS rule could lead donor families to overwhelmingly elect to have their loved ones’ organs or tissue go to “not-for-profit” organizations at the expense of “for-profit” organizations (by as much as 80% according to recent polling).
- Americans want to make their decision for who should receive their organs and tissue based on science and technology, not tax status.
- Americans want “for-profit” and “non-profit” entities to be treated the same in rules and regulations.

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- Reducing "for-profit" organizations' ability to acquire tissue is likely to lead to less innovation, fewer jobs and less taxes to the Federal government, as "for-profit" organizations are actually "taxpayers".

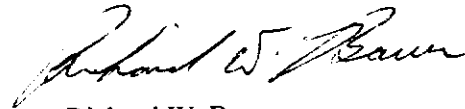
- There are few differences between "for-profit" and "not-for-profit" organizations beyond tax status.

- The proposed rule appears to focus on four main organs, excluding the very real and different treatment and analysis that should be afforded to other tissue, such as musculoskeletal tissue.

In closing, Osteotech, as a for-profit company within the tissue banking system, is in full support of providing relevant information to individuals considering the opportunity to donate tissue to help those in need. We take very seriously our role as a steward of the gift of donation, and are committed to maximizing the benefit of each and every one of those gifts. Therefore, we propose that the following language be used in lieu of item #5 of 42 CFR Part 486, Section 486.342;

"Consenting individuals must be informed that tissue will be collected, processed, stored and distributed in an efficient manner, following strict ethical guidelines, that minimizes costs and maximizes the benefit to patients and society, and that this will require the involvement of multiple organizations".

Thank you,



Richard W. Bauer

Attachment

CC:RWB/rbk

References

- ¹ Polly DW, Ackerman SJ, Shaffrey CI, Ogilvie JW, Wang JC, Strakla SW, Mafilios MS, Heim SE, Sandhu HS. A cost analysis of bone morphogenetic protein versus autogenous iliac crest bone graft in single-level anterior lumbar fusion. *Orthopedics* October 2003, Vol 26 No 10:1027-1037.
 - ² Deyo RA, Ciol MA, Cherkin DC, Loeser JD, Bigos SJ. Lumbar spinal fusion. A cohort study of complications, reoperation and resource use in the Medicare population. *Spine* 1993;18:1463-1470.
 - ³ Watters WC 3rd, Levinthal R. Anterior cervical discectomy with and without fusion. Results, complications, and long term follow-up. *Spine* 1994;20:2343-2347.
- * Poll conducted by Moore Information, Inc. among a representative sample of 800 registered voters nationwide. The survey was conducted April 17-20, 2005. The margin of error is +/- 3% at the 95% confidence level.